> Yet the examiner now has taken the position that:
>
> The critical date being urged in the declaration under 37 C.F.R. 1.131 is not agreed. A careful examination of the parent application s.no. 07/337460 teaches the dosage range as "twice daily". It is the position of the . . . examiner that "twice daily" includes dosage at "night or evening claimed". The date of the parent application is 4/13/89.

Advisory action, dated April 19, 1996. Accordingly, applicant understands the examiner's position to be that the Rule 131 declaration is inadequate to antedate the O'Neill patent because its parent application, which issued as Evenstad *et al.*, U.S. patent No. 5,126,145 (1992), provides support for a method of treating hyperlipidemia comprising the administration of niacin once a day in the evening or at night. Applicant respectfully traverses this basis for maintaining the rejection.[1]

The following table compares the disclosure of Evenstad *et al.*, noted by the examiner, with the teaching of O'Neill *et al.*:

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[1] Applicant will address the issue of the Evenstad disclosure as framed by the examiner. Applicant notes, however, that if the Evenstad patent truly taught applicant's claimed method, then the Evenstad patent would be prior art under §102(b) and the issue of whether the O'Neill patent is prior art would be moot.

Reference	Frequency of Administration	Time of Administration
Evenstad patent (column 5, lines 58-60): "Tablets can be scored to permit dasy [*sic*] breakage into smaller doses for titration up to the standard 750 mg. dose given twice daily."	Two times per day	Unknown
O'Neill patent (column 3, lines 15-19): "[O]ne or more, *e.g.*, about 1-4, of said unit dosage forms [of niacin should] be ingested by a human patient once daily, with the evening meal, or after the evening meal and before bedtime, in order to lower serum lipids or lipid components . . . ."	Once per day	With the evening meal, or after the evening meal

As the table illustrates, the teachings of the Evenstad and O'Neill patents can be distinguished at least because: (1) Evenstad *et al.* state that niacin can be given <u>twice a day</u>, while O'Neill *et al.* state that niacin must be given <u>once a day</u>, and (2) O'Neill *et al.* state that <u>niacin must be given with (or after) the evening meal</u>, while Evenstad *et al.* provide <u>no guidance about the timing of niacin administration</u>. Thus, the "twice daily" teaching of the Evenstad patent cannot support the administration of niacin with (or after) the evening meal, as taught by the O'Neill patent.

2. The Rule 132 Declaration of Dr. Arthur Raines Provides Additional Evidence That the Evenstad Method Fails to Suggest the Method of O'Neill et al.

As a preliminary matter, applicant wishes to address the issue of the timeliness of the attached Rule 132 declaration. According to §716.01 of the *Manual of Patent Examining Procedure* (September 1995), a Rule 132 declaration filed after final rejection is considered timely if applicant makes a satisfactory showing under 37 CFR §1.116(b). Under the standard provided by Rule 116(b), applicant is required to make a showing of good and sufficient reasons why the declaration is necessary and why it was not presented earlier.

In the present case, the Rule 132 declaration is necessary to explain why the Evenstad patent does not support the disclosure in the O'Neill patent regarding once-a-day dosing of niacin. Applicant did not present the declaration at an earlier point in prosecution because the examiner raised this issue *for the first time* in the advisory action. That is, the present request for reconsideration is the first opportunity for applicant to address the issue of whether the Evenstad disclosure suggests the method of O'Neill *et al.* Accordingly, the attached Rule 132 declaration is timely and seasonably filed.

In the attached declaration, Dr. Arthur Raines states that his review of the Evenstad patent revealed that the document discloses a formulation of a sustained release tablet suitable for use with highly water soluble drugs. See paragraph 3 of the Declaration Under 37 CFR §1.132 of Dr. Arthur Raines, which is attached to this response as Exhibit A. Moreover, Dr. Raines found that the Evenstad patent teaches that niacin, which is the water soluble agent used as an example of the invention, could be administered twice a day. *Id.* at paragraph 4. Yet Dr. Raines attests that at no point in the Evenstad patent is the issue of a specified time of administration of niacin mentioned, nor is the issue of diurnal variation in lipid biosynthesis addressed.

Id. That is, Dr. Raines has observed that the Evenstad patent fails to teach the timing of the dose of niacin at a particularly appropriate part of the day to enhance efficacy. *Id.*

Dr. Raines concludes that:

> In summary, the Evenstad patent does not teach or even suggest the O'Neill method of administering niacin at a time of day targeted to coincide with the time at which cholesterol is maximally synthesized in the human liver.

Id. at paragraph 6. Finally, Dr. Raines emphasizes that the "once daily, diurnal variation-related dose of niacin described by O'Neill cannot be said to follow from the two dose, diurnal variation-unrelated regimen of Evenstad." *Id.*

Thus, Dr. Raines attests that the Evenstad patent does not suggest the O'Neill method of administering niacin once per day with (or after) the evening meal.

3. *The Examiner's Allegation That the Present Invention and the O'Neill Patent Claim the Same Invention Requires Clarification*

To date, the examiner has cited the O'Neill patent as prior art under §102(e), directing applicant to "[s]ee col. 1, lines 46 et seq. for nicotinic acid and the method of use, see col. 3-4 and see the examples." Office action of June 30, 1995, at page 3. That is, the examiner has taken the position that applicant's invention is anticipated by the specification of O'Neill *et al.*

In contrast, the examiner now has taken the position that:

> [A] declaration under 37 C.F.R. 1.131 can not [*sic*] overcome a patent claiming the same invention as claimed. See M.P.E.P. 715.05 and M.P.E.P. 2300.01.

Advisory action, dated April 19, 1996. That is, the examiner now has taken the position that applicant's invention is unpatentable in view of the claims of O'Neill *et al.* Applicant respectfully submits that the recharacterization of the O'Neill patent as

prior art under §102(g) requires the removal of finality and a clarification of the examiner's basis for rejection.[2]

According to the *MPEP*:

> A 37 CFR 1.131 affidavit is ineffective to overcome a United States patent, not only where there is a verbatim correspondence between claims of the application and of the patent, but also where there is no patentable distinction between the respective claims.

Id. at §715.05. Since there is no verbatim correspondence between the presently claimed invention and the O'Neill patent claims, applicant assumes that the examiner has taken the position that there is no "patentable distinction" between the two sets of claims. Applicant respectfully asserts that the examiner should explain the basis for this position, including an identification of the present claims and the O'Neill claims that, allegedly, are not patentably distinct.

Moreover, applicant notes that *MPEP* §706.02(a) instructs examiners to initially determine whether a reference is prior art under §102(a), §102(b) or §102(e). The *MPEP* further explains that:

> When the claims of the reference and the application are directed to the same invention or are obvious variants, an affidavit or declaration under 37 CFR 1.131 is not an acceptable method of overcoming the rejection . . . . Under these circumstances, the examiner must determine whether a double patenting rejection or interference is appropriate. If there is a common assignee or inventor between the application and patent, a double patenting rejection must be made. See MPEP § 804. <u>If there is no common assignee or inventor and the rejection under 35 U.S.C. 102(e) is the only possible rejection, the examiner must determine whether an interference should be declared.</u>

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[2] The examiner clearly has suggested the need for an interference between the present application and the O'Neill patent. Since an interference is based on a patent that is prior art under §102(g), the examiner has introduced a new rejection based on the O'Neill patent as a §102(g) reference. See *MPEP* §2138.01.

Id. at §706.02(b) (emphasis added). Applicant understands that the examiner has concluded that an interference should be declared.

Yet the *MPEP* also teaches that, in determining whether an interference is necessary, an examiner must find that at least one of applicant's claims is "allowable and in good form." *MPEP* §2301.01. Accordingly, applicant respectfully requests the examiner to identify the allowable claim that is directed to the same invention as claimed by O'Neill *et al.*, or is an obvious variant thereof.

In light of the declaration and remarks above, applicant requests the examiner to withdraw the rejection to the claims under 35 USC §102(e). Reconsideration of the claims is respectfully requested.

CONCLUSION

Applicant requests reconsideration of the claims on their merits. If Examiner Venkat should have any questions or believes a telephone discussion would expedite prosecution, the examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

May 23, 1996
Date

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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY DEFICIENCY OR CREDIT ANY OVERPAYMENT TO DEPOSIT ACCOUNT NO. 19-0741.